Section II (Remarks)

A. Summary of Amendment to the Claims

By the present amendment, claims 1, 4-11, 26, and 30 have been amended, and claims 2 and 14 have been cancelled. Claims 22-25 and 31 have been withdrawn. No new matter within the meaning of 35 U.S.C. 132 has been introduced by the foregoing amendments.

B. Response to Rejections Under 35 U.S.C. 112

In the December 1, 2006 Office Action, claims 1-21 and 26-30 were rejected under 35 U.S.C. 112, second paragraph, as being unclear for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. In particular, the Examiner objected to the recitation in claims 1, 11, and 26 of a "plastically deformable outer layer," stating:

> This limitation is unclear since 'plastically deformable' is a relative characteristic of a material. In fact, every solid substance can be 'plastically deformed' provided a sufficient deforming force is applied.

December 1, 2006 Office Action, page 3.

In response to such rejection, claims 1, 11, and 26 have been amended to recite "an outer surface of a non-elastomeric material." Support for such amendment is provided in the originally-filed disclosure, for example, at paragraphs [0006]-[0009], which discuss the shortcomings of fluidic interconnects utilizing elastomeric materials, and the desirability of eliminating problems associated with the use of elastomeric materials in microfluidic devices, particularly when such devices are applied to end uses such as liquid chromatography.

C. Response to Rejections Under 35 U.S.C. 103

The December 1, 2006 Office Action contained rejections of various claims under 35 U.S.C. 103, including:

- a rejection of claims 1-11, 14-21, and 26-30 as unpatentable for obviousness over U.S. Patent No. 7,060,227 to Staats ("Staats"); and
- a rejection of claims 12 and 13 as unpatentable for obviousness over Staats in view of U.S. Patent Application Publication No. 2004/0011648 to Paul et al. ("Paul").

Such rejections are traversed in application to the claims as presented herewith.

1. Law Regarding Obviousness

Concerning §103 obviousness rejections, three requirements must be met for a *prima facie* case of obviousness. First, **the prior art reference(s) must teach all of the limitations of the claims.** MPEP § 2143.03. Second, there must be a motivation to modify the reference or combine the teachings to produce the claimed invention. MPEP § 2143.01. Third, a reasonable expectation of success is required. MPEP § 2143.02. In addition, the teaching or suggestion to combine and the expectation of success must both be found in the prior art and not based on applicant's disclosure. MPEP § 2143. A further consideration, which applies to all obviousness rejections, is that "**[a] prior art reference must be considered in its entirety,** *i.e.*, as a whole, **including portions that would lead away from the claimed invention.** *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540, 220 USPQ 303 (Fed. Cir. 1983), cert. denied, 469 U.S. 851 (1984)." (emphasis in original; MPEP 2141.02).

2. Disclosure of Staats

Staats teaches the assembly of microfluidic devices from a channel-defining substrate aligned, mated, and compressed against a cover or another substrate to form enclosed channels and other features. E.g., Staats FIGS. 1-5, 13 & 18; col. 6, lines 60-62 ("**when a second substrate is aligned with the first substrate, the microfluidic channels and other features are properly enclosed**"). For example, Staats FIGS. 1-3 illsutrate various channel-defining substrates mated to covers, and Staats FIGS. 4-5 illustrate substrate-to-substrate interfaces. Microfludic device portions (e.g., lacking covers in at least FIGS. 6-10) with various protrusions and raised wall features defining open channels are illustrated in Staats FIGS. 6-13. Closed channels are formed in devices according to Staats only when one substrate is covered by another substrate or cover.

To provide a fluidic interface with a microfluidic device, Staats teaches the use of **raised capillaries** 130, 140. See, e.g., Staats FIGS. 12-13, as reproduced below:

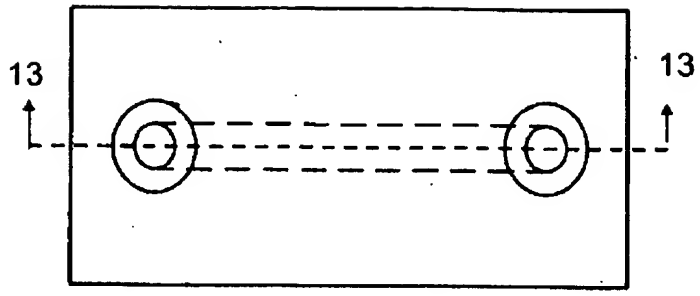


FIG. 12

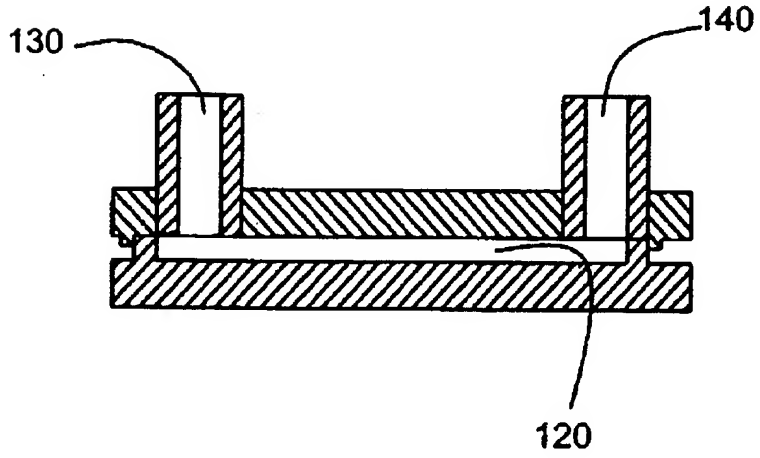


FIG. 13

In describing such Figures, Staats provides:

> FIGS. 12 and 13 provide top and sectional views of an **assembled microfluidic device** with a single raised channel 120 **with capillaries 130 and 140 attached to channel access ports which provide access to the channel for sample and buffer input or transport to a spectrometer for analysis**.

Staatus, col. 8, lines 32-36 (emphasis added).

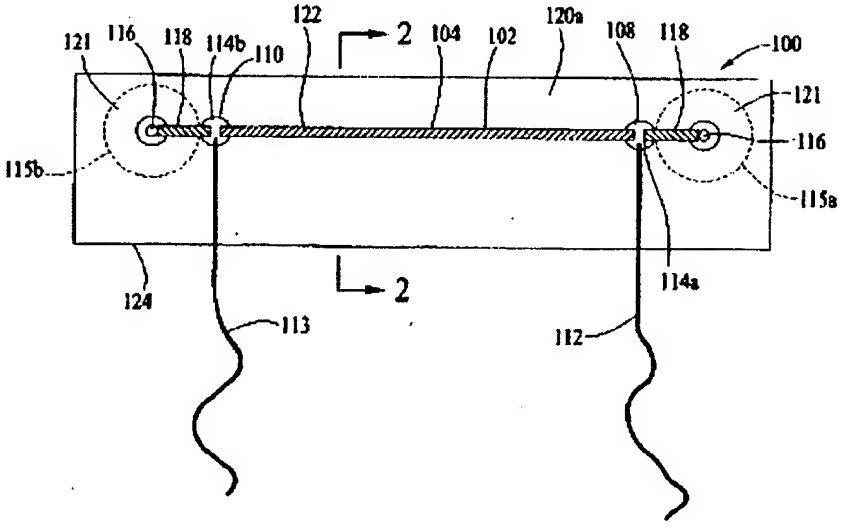
Nothing in Staats teaches or remotely suggests any retractable element that is external to a channel-defining microfluidic device, let alone a retractable element having a continuous

raised feature surrounding an aperture, with the continuous raised feature being compressible into an outer surface or layer of the microfluidic device to permit fluid transfer between the retractable element and microfluidic device when the continuous raised feature is depressed into such outer surface or layer.

3. Disclosure of Paul

Paul discloses various flow devices including porous materials encapsulated within laminating materials to form channel enclosures. To provide fluid interfaces to such devices, Paul teaches the use of either "pigtailed capillaries" affixed by lamination (e.g., Paul, ¶ [0027] & FIG. 1) or "conventional HPLC fittings ... that are bonded by bonding material to an upper substrate " (e.g., Paul, ¶ [0032] & FIG. 4). FIGS 1 and 4 of Paul, which illustrate these alternative bonding methods, are reproduced below.

Fig. 1



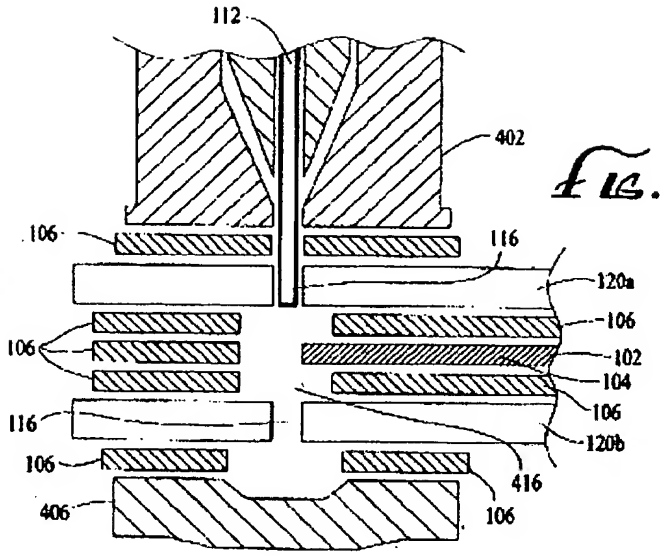


FIG. 4

Nothing in Paul teaches or remotely suggests any retractable element that is external to a channel-defining microfluidic device and has a continuous raised feature surrounding an aperture, with the continuous raised feature being compressible into an outer surface or layer of the microfluidic device to permit fluid transfer between the retractable element and microfluidic device when the continuous raised feature is depressed into such outer surface or layer.

4. Patentable Distinctions of Pending Claims Over Staats and Paul

Claims 1, 3-13, 15-21, and 26-30 include three independent claims, namely, claims 1, 11, and 26. Such claims are reproduced below for the convenience of the Examiner, with various features distinguishing the cited art provided in bold.

1. A gasketless fluidic interface comprising:

a microfluidic device having an outer surface of a non-elastomeric material and defining a first aperture, the **microfluidic device further having a substantially enclosed internal microfluidic channel** disposed substantially parallel to the outer surface and in fluid communication with the first aperture;

a **retractable element external to the microfluidic device**, the **retractable element including a mating surface defining a second aperture**, wherein the **mating surface has a raised feature** protruding from the mating surface, **and the raised feature comprises a continuous raised feature that surrounds the second aperture**; and

a compression element **adapted to depress the raised feature into the outer surface to plastically deform the outer surface along the raised feature** and thereby **permit the transfer of fluid between the first aperture and the second aperture** while preventing unintended fluidic leakage between the mating surface and the outer surface adjacent to the first aperture, without collapsing the internal microfluidic channel.

11. A gasketless fluidic interconnect comprising:

a substantially planar microfluidic device having a plurality of device layers and defining a **substantially enclosed internal microfluidic channel**, the plurality of device layers including an outer layer of a non-elastomeric material and defining a first aperture in fluid communication with the internal microfluidic channel;

a **retractable mating surface external to the microfluidic device and defining a second aperture, the retractable element having a protruding feature aligned with the first aperture, wherein the protruding feature comprises a continuous wall that surrounds the second aperture**; and

an **actuator adapted to depress at least a portion of the protruding feature into, and to plastically deform, the outer layer adjacent to the first aperture to provide sealing engagement between the outer layer and the mating surface and permit the transfer of fluid between the first aperture and the second aperture**.

26. A system for performing high throughput pressure-driven liquid chromatography, the system comprising:

a microfluidic device having an outer surface of a non-elastomeric material and defining a plurality of device apertures, the **microfluidic device further having a plurality of substantially enclosed internal separation columns** adapted for parallel operation and in fluid communication with the plurality of apertures;

a **retractable seal plate external to the microfluidic device**, the retractable seal plate **including a mating surface having a plurality of raised features protruding from the mating surface, wherein each mating surface defines a seal plate aperture registerable with a corresponding device aperture of the plurality of device apertures, and each raised feature comprises a continuous raised feature that surrounds a seal plate aperture**; and

an **actuator adapted to depress at least a portion of the plurality of raised features into, and to plastically deform, the outer surface, adjacent to the plurality of device apertures to provide sealing engagement between the outer surface and the mating surface, and to permit the transfer of fluid between each seal plate aperture and a corresponding device aperture.**

As indicated previously, Staats teaches the assembly of microfluidic devices by pressing either a cover or substrate against an open-channel-defining substrate to form enclosed channels. Once Staats' enclosed-channel-defining microfluidic device is formed, nothing in Staats teaches or remotely suggests than any structure external to the microfluidic device should be depressed against the microfluidic device to plastically deform an outer surface or layer of the device to form a fluidic interface. Furthermore, nothing in Staats teaches any structure external to a microfludic device that defines an aperture surrounded by a raised feature for depression into an external portion of a microfluidic device.

To the contrary, Staats teaches that fluidic interfaces with assembled (i.e., closed-channel-defining) microfluidic devices should be made by way of integral raised capillaries that protrude outward **from the microfluidic device**. See, e.g., Staats FIG. 13, as reproduced above. The present claims, which require a retractable element that is external to the microfluidic device and defines raised features, is structurally distinct from and incompatible with such teaching of Staats. One object of the present invention is to provide a reliable fluid-tight connection with a microfludic device of which at least a portion is substantially planar. See, e.g., Applicants' FIG. 4A, as reproduced below:

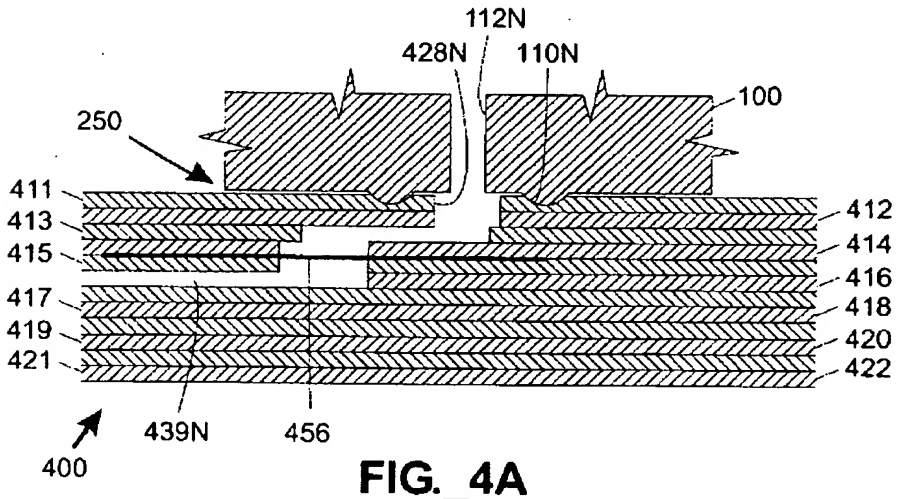


FIG._4A

Note that the illustrated portion of the microfluidic device 400 (which defines a substantially enclosed separation channel 439N) showns an outer surface (or outer layer 411) lacking any protruding features. **Only the retractable element 100 defines a protruding continuous (e.g., annular) feature 110N**, and such feature 110N is depressed into the outer layer 411 of the microfludic device to form the sealing interface. An aperture 112N defined in the retractable element 100 is registered with a corresponding aperture 428N of the microfluidic device 100 to permit fluid transfer between the two.

Staats fails to teach in combination: a microfluidic device having a substantially enclosed channel, with an aperture-defining retractable element external to the microfluidic device, and a raised continuous feature surrounding such aperture, with a compression element adapted to depress the raised feature into an outer surface of the microfluidic device to plastically deform such surface and permit transfer of fluid between the compression element and the microfluidic device.

Paul fails to remedy the deficiencies in Staats' disclosure in this regard. With respect to fluidic interfaces, Paul teaches the use of either laminated pigtail fitting connections or conventional HPLC fittings.

Since the cited art fails to teach all of the limitations of independent claims 1, 11, and 26, no *prima facie* case of obviousness has been established pursuant to MPEP 2143 – whether as to the independent claims or the claims depending therefrom. Accordingly, withdrawal of the rejections under 35 U.S.C. 103 is warranted, and respectfully requested.

CONCLUSION

Based on the foregoing, all of applicants' claims 1, 3-13, 15-21, and 26-30 are therefore patently distinguished over the art, and in form and condition for allowance. The examiner is requested to favorably consider the foregoing, and to responsively issue a Notice of Allowance. If any issues require further resolution, the examiner is requested to contact the undersigned attorney at (919) 419-9350 to discuss same.

Respectfully submitted,

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